K030149

Section C. 510(k) Summary

Submitter: Avail Medical Products, Inc.
201 Main Street, Suite 1600
Fort Worth, Texas 76102

MAR 2 0 2003

Contact: Courtland Imel (972) 929-4800

Name of Device: Medtronic® MiniMed® Paradigm® Sof-site

Predicate Device: Medtronic® MiniMed® Paradigm™ Quick-set™, models MMT-396, MMT-397, MMT-398, and MMT-399 and Medtronic® MiniMed® Paradigm™ Sof-set™ Ultimate™ QR® infusion sets, models MMT-317 and MMT-318

Description of the New Device: The Medtronic MiniMed Paradigm Sof-site infusion sets, models MMT-359S6, MMT-359M6, MMT-359L6, MMT-359S9, MMT-359M9, and MMT-359L9, are infusion administration sets that connect to a Medtronic MiniMed medication reservoir.

The infusion sets attach to the medication reservoir by means of a proprietary connector. Fluid is administered through multi-layer tubing to an indwelling catheter. The indwelling catheter is introduced into the subcutaneous tissue of the user by means of a removable introducer needle. The introducer needle is housed in a plastic needle hub and protected by a plastic needle guard. The needle guard is removed before insertion. The indwelling catheter is affixed to a plastic base unit. The plastic base unit functions as a site for connection and disconnection. The adhesive patch is integral to the base and is used to secure the unit to the user.

Intended Use of the New Device: The Medtronic MiniMed Paradigm Sof-site, models MMT-359S6, MMT-359M6, MMT-359L6, MMT-359S9, MMT-359M9, and MMT-359L9, are intended for the subcutaneous infusion of medicine, including insulin, from a Medtronic MiniMed infusion pump. The set is not intended nor indicated for use with blood.

Comparison of the Technological Features of the New Device and Predicate Devices: The modified device and the lawfully marketed predicate devices contain similar materials of construction. Features of the modified device are comparable to those of the predicate devices with the exception of the distal connect/disconnect mechanism. The modified mechanism does not require specific alignment to the site as is currently required in the predicate devices. This modification does not affect the safety or effectiveness of the device.

Signed,

Courtland Imel
Manager, Quality
Avail Medical Products, Inc.

®MiniMed, Quick-serter, Quick-set, Soft-set Ultimate QR, Soft-set, and QR are Registered Trademarks of Medtronic MiniMed
™Paradigm, Quick Release, Ultimate, and Sof-site are Trademarks of Medtronic MiniMed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Ms. Carroll Councilman
Avail Medical Products, Incorporated
1900 Carnegie Avenue
Santa Ana, California 92705

Re: K030149
Trade/Device Name: Medtronic MiniMed Paradigm Sof-site Infusion Sets, Models MMT359S6, MMT359M6, MMT359L6, MMT359S9, MMT359M9 and MMT359L9
Regulation Number: 880.5440
Regulation Name: Intravascular Administrative Set
Regulatory Class: II
Product Code: FPA
Dated: January 14, 2003
Received: January 15, 2003

Dear Ms. Councilman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030149

INDICATIONS FOR USE

510(k) Number:

Device Name: Medtronic MiniMed Paradigm Sof-site infusion sets, models MMT359S6, MMT359M6, MMT359L6, MMT359S9, MMT359M9, and MMT359L9

Indications for Use: The Medtronic MiniMed Paradigm Sof-site infusion sets are indicated for the subcutaneous infusion of medicine, including insulin, from a Medtronic MiniMed infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices